REMARKS

Drawing

Applicants hereby submit drawing corrections as required in the instant Office Action.

Specification

Applicants hereby submit an abstract of the disclosure on a separate sheet as requested by the Examiner.

The 35 U.S.C. §112 Rejection

Claims 1, 5-13 and 15-18 were rejected under 35 U.S.C. §112, first paragraph, for lack of deposit. The rejection is respectfully traversed.

Claim 1 has been amended to recite a genetically engineered mutant *C. fetus* strain derived from strain 23D (PTA-4754). The mutant *C. fetus* strain has a DNA cassette inserted into the coding sequence of a *sap*A homolog. The expression of said DNA cassette results in surface expression of a chimeric protein comprising a heterologous protein encoded by the DNA cassette. The instant specification teaches mutant *C. fetus* strain was derived from wild

type *C. fetus* strain 23D into which a DNA cassette was inserted using plasmids pKO500 or pKO505. *C. fetus* strain 23D has been deposited at ATCC as PTA-4754, *E. coli* HB101 with plasmid pK0500 was deposited as PTA-4751, and *E. coli* DH5-a with plasmid pK0505 was deposited as PTA-4752. Consequently, Applicants submit that one of ordinary skill in the art would readily derive a mutant *C. fetus* strain as claimed in claim 1 using the materials and methods disclosed herein.

Claim 10 has been amended to recite a mutant *C. fetus* strain derived from recA mutant strain 97-211 (PTA-4753). The claimed mutant strain has been deposited and it can express only one S-layer protein encoded by one *sap*A homolog due to a *recA* mutation that results in no functional RecA protein expression. Claim 15 has been amended to recite a strain of *Escherichia coli* (PTA-4750) modified to express the surface array proteins C, D, E and F of *C. fetus* strain 23D. *E. coli* DH5-a containing plasmid pIR100 that encodes sapCDEF of *C. fetus* strain 23D has been deposited at ATCC as PTA-4750. Therefore, one of ordinary skill in the art can readily use the plasmid to construct the claimed bacterial strain.

In view of the above deposits and amendments, Applicants respectfully request that the rejection of claims 1, 5-13 and 15-18 under 35 U.S.C. §112, first paragraph, be withdrawn.

Claims 1, 5-13 and 15-18 were rejected under 35 U.S.C. §112, first paragraph, for lack of written description. The rejection is respectfully traversed.

The Examiner contends that reciting *sapA* homologs would read on *sapB, sapC, sapD, sapE* and *sapF*. Applicants respectfully disagree. The instant invention is drawn to bacteria comprising *sap*A homolog of strain 23D, which is a strain of type A serotype (see abstract of Dworkin et al., J. Biol. Chem. 270:15093 (1995)). In contrast, *sapB* gene is derived from cells of type B serotype (see abstract of Dworkin et al., J. Biol. Chem. 270:15093 (1995)). Therefore, *sap*A homolog of strain 23D would only read on homologs derived from type A cells; it does not read on *sapB* derived from type B cells.

Applicants reiterate that it is clear to one of ordinary skill in the art that *sapC, sapD, sapE* and *sapF* are not *sapA* homologs. These other genes are different and distinct from *sapA* homologs,

and they serve functions different from that of *sapA* homologs. As it was taught in the instant specification, the *sapCDEF* operon comprises four overlapping genes that encode a type I protein secretion system. The Examiner contends that homolog is generally understood to define an evolutionary relatedness. According to this definition, it is obvious to one of ordinary skill in the art that a surface protein such as sapA homolog does not have evolutionary relatedness with proteins such as sapCDEF that constitute cellular transport and secretion machinery. Furthermore, the Examiner has not provided any prior art reference that indicate that a person having ordinary skill in this art would regard sapA homolog and sapCDEF proteins as evolutionarily related.

Claim 10 has been amended to recite a mutant *C. fetus* strain derived from recA mutant strain 97-211 (PTA-4753). The claimed mutant strain has been deposited and it can express only one S-layer protein encoded by one *sap*A homolog due to a *recA* mutation that results in no functional RecA protein expression. Claim 15 has been amended to recite a strain of *Escherichia coli* (PTA-4750) modified to express the surface array proteins C, D, E and F of *C. fetus* strain 23D. *E. coli* DH5-a containing plasmid pIR100 that

encodes sapCDEF of *C. fetus* strain 23D has been deposited at ATCC as PTA-4750. Claim 16 has been amended to recite a bacteria comprising *sap*A homolog of *C. fetus* strain 23D.

In view of the deposits and amendments described above, Applicants submit that the written description requirement has been satisfied in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. Accordingly, Applicants respectfully request that the rejection of claims 1, 5-13, 15-18 under 35 U.S.C. §112, first paragraph, be withdrawn.

Claim Objections

Claims 7, 12, 15-17 were objected to for informalities. Applicants submit that appropriate corrections have been made as suggested by the Examiner.

New Grounds of Rejection

Claims 1, 7, 9 and 18 were rejected under 35 U.S.C. §112, first paragraph, for lack of possession of the claimed invention. The rejection is respectfully traversed.

Claims 7 and 18 were rejected for conflicting with claim 1 and reciting sub-genus of species that lacks descriptive support in the specification. Claims 7 and 18 have been canceled. Accordingly, Applicants respectfully request that the rejection of claims 1 and 9 under 35 U.S.C. §112, first paragraph, be withdrawn.

Claims 6, 11, 13 and 18 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The rejection is respectfully traversed.

Claim 6 was rejected for lack of clarity. Claim 6 has been canceled and the limitations of claim 6 are incorporated into claim 1. Claim 11 has been amended as suggested by the Examiner.

Claim 12 was rejected for lack of clarity. Claim 12 has been amended to recite a mixture of mutant *C. fetus* strains. These mutants are constructed in which a single *sapA* homolog of each mutant is engineered to encode a chimeric protein representing a different heterologous antigen in each of said mutants. Each mutant is also RecA-deficient due to mutation in *recA*.

Claim 13 was rejected for reciting "pharmacologically effective dose". The claim has been amended to delete the phrase. Claim 18 has been canceled.

In view of the above amendments, Applicants submit that the claims have been amended to obviate the rejection. Accordingly, Applicants respectfully request that the rejection of claims 6, 11, 13 and 18 under 35 U.S.C. §112, second paragraph, be withdrawn.

The 35 U.S.C. §102 Rejection

Claims 1, 5 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by **Dworkin** et al. (1995, J. Biol. Chem., vol. 270). The rejection is respectfully traversed.

Dworkin et al. teach a genetically mutated strain of *C. fetus* strain 82-40 LP3. In contrast, the present invention is drawn to genetically engineered mutant *C. fetus* strain derived from strain 23D. The mutant *C. fetus* strain has a DNA cassette inserted into the coding sequence of a *sap*A homolog. The expression of said DNA cassette results in surface expression of a chimeric protein comprising a heterologous protein encoded by the DNA cassette. **Dworkin** et al. do not teach or suggest a *C. fetus* mutant as claimed

herein. Since **Dworkin** et al. do not teach or suggest each and every aspect of the present invention, **Dworkin** et al. do not anticipate claim 1 of the present invention. Accordingly, Applicants respectfully request that the rejection of claims 1, 5 and 8 under 35 U.S.C. §102(b) be withdrawn.

This is intended to be a complete response to the Office Action mailed April 1, 2003. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

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